

Board of Pharmacy

ADDENDUM TO Final Statement of Reasons

Subject Matter of Proposed Regulation: Wholesaler Self-Assessment Form

Title 16 Sections Affected: Add 1784

Updated Information

The Initial Statement of Reasons is included in this rulemaking file. The information contained therein accurately reflects the board's position regarding the adoption of the above section.

A few nonsubstantive changes were made to the form being incorporated by reference. The changes included correcting grammar, punctuation and typographical errors made in legal citations referenced. It was determined upon review of these changes, that a 15-day notice was not necessary.

In addition, the language of the section was also updated to reflect the correct revision date of the form being incorporated. Specifically, the revision date was changed from August 14, 2006 to December 14, 2006.

This section establishes requirements for the designated representative in charge (DRC) of a licensed wholesaler to complete a self-assessment form to ensure compliance with pharmacy law. This self-assessment form is a compilation of the requirements detailed in pharmacy law that a wholesaler must comply with. The form was designed to assist wholesalers as well as the respective designated representative by increasing their knowledge of relevant legal requirements as well as a mechanism to confirm their compliance with state and federal law. Public safety is greatly increase as a result of this compliance.

This form also provides an easy reference tool for employees seeking guidance with relevant state and federal law specific to the wholesaling of dangerous drugs.

This proposal would make the pharmacy inspection process more meaningful by allowing board inspectors to focus their efforts on areas of concern with the DRC and assist in more readily ensure a wholesalers compliance with pharmacy law.

Summary of Comments Received During the 45-Day Comment Period:

No comments were received during the 45-day comment period.. No public comment hearing was requested in connection with this rulemaking and none was held.

Local Mandate:

None

Business Impact:

This regulation will not have a significant adverse economic impact on businesses. This determination was based on the absence of testimony indicating adverse economic impact regarding these rulemaking proposals at the information hearings held by the board and during the 45-day comment period.

Specific Technologies or Equipment:

This regulation does not mandate the use of specific technologies or equipment.

Consideration of Alternatives:

No reasonable alternative to the regulation would be either more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to the affected persons than the proposed regulation.